Initial Approval: October 8, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Alpha₁-Proteinase Inhibitors

PROVIDER GROUP: Pharmacy

Professional

MANUAL GUIDELINES: The following drug(s) requires prior authorization:

Aralast NP® (Alpha₁-Proteinase Inhibitor (Human)) Glassia® (Alpha₁-Proteinase Inhibitor (Human)) Prolastin C® (Alpha₁-Proteinase Inhibitor (Human)) Zemaira® (Alpha₁-Proteinase Inhibitor (Human))

CRITERIA for all agents: (must meet all of the following)

• Patient must be 18 years of age or older

- Patient must be a non-smoker or be receiving smoking cessation treatment
- · Patient must be diagnosed with severe Alpha1-PI deficiency and clinically have evident emphysema
 - \circ ATT serum concentration <11 μ mol/L (80mg/dL if measured by radial immunodiffusion or 50 mg/dl if measured by nephelometry)
 - o FEV₁ between 30 and 65% or a rapid decline in FEV₁ >120 ml/yr
 - o Phenotype must be PiZZ, PiZ (null), Pi (null)(null)
- Must be prescribed by or in consultation with a pulmonologist
- Maximum dose of 60mg/kg once a week

Length of Approval: 3 months